APR 2 7 2001

510(k) Summary

As Required by 21 section 807.92 (c)

1 of 2

K010789

1-Submitter Name: A & A Medical, Inc.
2-Address: 9370 Industrial Trace
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jihad Mansour
6-Date summary prepared: March 12th, 2001
7-Device Trade or Proprietary Name: EZ-PORT
8-Device Common or usual name: Trocar/cannula
9-Device Classification Name: Cannula, Surgical, General & Plastic Surgery
10-Substantial Equivalency is claimed against the following device:

- Genicon Trocar

11-Description of the Device:

The device is to be used by physicians in hospitals

EZ-PORT is indicated for use in laparoscopic surgery and has application in gynecologic, general, thoracic and urology endoscopic procedures to establish a port of entry for instrumentation. EZ-PORT is a sterile and single use trocar system that consists of 3 main components.

- The main trocar. It has a pyramidal 14-degree stainless steel tip to provide easier insertion. Its handle is enlarged to provide a more positive fit in the surgeon's palm. A removable plastic safety cover is provided at the tip to protect personnel from injuries while handling
- The Cannula. The casing is clear for visualization of instrument and tissue passage. The threads are of reverse trapezoidal fascia. They provide an easier insertion as well as a positive anchoring during instrument use. From the casing, an insufflation port extends and provides a "finger grip" during device insertion, and it is provided with a male luer cap
- The valve. A double wall valve lock which assists in maintaining the valve position. It is a tapered membrane assembly that provides a more positive seal around the instrument, while the silicon membrane was designed to reduce friction during instrument use. A pull-tab is added to facilitate removal of the valve during specimen retrieval

• Product is available in two different sizes, short (70mm) and long (100mm). Product is packaged either with single cannula (single pack) R65-995 for short and R65-997 for long, or with two cannulas (dual pack) R65-995-1 for short and R65-997-1 for long, or three cannulas (tri pack) R65-995-2 for short and R65-997-2 for long.

12-Intended use of the device:

EZ-PORT is a single use disposable sterile trocar/cannula system intended for use in laparoscopic surgery and has application in gynecologic, general, thoracic and urology endoscopic procedures to establish a port of entry for instrumentation

13-Safety and Effectiveness of the device:

This device (**EZ-PORT**) is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that **EZ-PORT** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 982472
Attachments inside notification submission file	REFER TO TABLE ON PAGE 11 OF 12 FOR DETAILS
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Similar (Ethylene Oxide with different parameters)
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

Mr. Jihad Mansour
Quality Assurance, Regulatory Affairs Manager
A & A Medical, Inc.
9370 Industrial Trace
Alpharetta, Georgia 30004

Re: K010789
Trade/Device Name: EZ-PORT
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: March 12, 2001
Received: March 15, 2001

Dear Mr. Mansour:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010789

Device Name: EZ-PORT

Indications For Use:

EZ-PORT IS INDICATED FOR USE IN LAPAROSCOPIC SURGERY AND HAS APPLICATION IN GYNECOLOGIC, GENERAL, THORACIC AND UROLOGY ENDOSCOPIC PROCEDURE TO ESTABLISH A PORT OF ENTRY FOR INSTRUMENTATION

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010789 MNM

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)